EXHIBIT N

Case 1:01-cv-12257-PBS Document 6183-16 Filed 06/26/09 Page 2 of 11

Vladeck, Ph.D., Bruce C.

May 4, 2007

New York, NY

Page 1

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

----X MDL NO. 1456

IN RE: PHARMACEUTICAL INDUSTRY : CIVIL ACTION:

AVERAGE WHOLESALE PRICE LITIGATION : 01-CV-12257-PBS

----X

THIS DOCUMENT RELATES TO: :

U.S. ex rel. Ven-A-Care of the : CIVIL ACTION:

Florida Keys, Inc. v. Abbott : 06-CV-11337-PBS

Laboratories, Inc. :

----X

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

----X

STATE OF ALABAMA, : CASE NO.

Plaintiff, : CV-05-219

V.

ABBOTT LABORATORIES, INC., : JUDGE

et al., : CHARLES PRICE

Defendants.

----X

Henderson Legal Services 202-220-4158

May 4, 2007

New York, NY

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Page 2
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  STATE OF WISCONSIN CIRCUIT COURT DANE COUNTY
                                                        IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
                                                     2
   -----X
                                                                STATE OF MISSOURI
                                                     3
   STATE OF WISCONSIN,
                            : CASE NO.
                                                       -----X
       Plaintiff, : 04-CV-1709
4
                                                       STATE OF MISSOURI, ex rel.,
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                                                     5
                                                       JEREMIAH W. (JAY) NIXON,
6
   AMGEN INC., et al.,
                                                       Attorney General,
                                                     6
7
       Defendants.
                                                     7
8
   -----X
                                                       MISSOURI DEPARTMENT OF SOCIAL
9
                                                        SERVICES, DIVISION OF MEDICAL : Case No.:
10
        IN THE COURT OF COMMON PLEAS
                                                       SERVICES.
                                                                             : 054-1216
11
         FIFTH JUDICIAL CIRCUIT
                                                               Plaintiffs, : Division
                                                    11
  -----X
                                                    12
12
                                                                        : No. 31
13
  STATE OF SOUTH CAROLINA, and : STATE OF
                                                    13
                                                             VS.
   HENRY D. McMASTER, in his official: SOUTH CAROLINA
14
                                                    14 DEY INC., DEY, L.P., MERCK KGaA, :
15
   capacity as Attorney General for : COUNTY OF
                                                    15 EMD, INC., WARRICK
   the State of South Carolina, : RICHLAND
16
                                                    16 PHARMACEUTICALS CORPORATION,
17
       Plaintiff,
                                                    17 SCHERING-PLOUGH CORPORATION, and :
18
                  : CIVIL ACTION:
                                                    18 SCHERING CORPORATION,
19 MYLAN LABORATORIES, INC. : 07-CP-40-0283
                                                    19
                                                               Defendants.
2.0
     Defendant.
                                                    20
                                                       ----x
21 -----X
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22
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                                           Page 3
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1
     IN THE COURT OF THE SECOND JUDICIAL CIRCUIT
                                                     1
                                                                    New York, New York
2
        IN AND FOR LEON COUNTY, FLORIDA
                                                     2
                                                                    Friday, May 4, 2007
3
   THE STATE OF FLORIDA
                                                     3
                                                     4
  ex rel.
                                                     5
                                                             Videotaped Deposition of BRUCE C.
   ----X
  VEN-A-CARE OF THE FLORIDA
                                                     6
                                                        VLADECK, Ph.D., a witness herein, called for
7 KEYS, INC., a Florida
                                                     7
                                                        examination by counsel for Abbott Laboratories in
8
   Corporation, by and through its :
                                                     8
                                                        the above-entitled matter, pursuant to Subpoena,
   principal officers and directors,:
                                                     9
                                                        the witness being duly sworn by JOMANNA DEROSA, a
   ZACHARY T. BENTLEY and
                                                    10
                                                       Notary Public in and for New York, taken at the
11
   T. MARK JONES.
                                                    11 offices of Jones Day, 222 East 41st Street, New
12
          Plaintiffs,
                                                    12 York, New York, at 8:38 a.m. on Friday, May 4,
                    : Civil Action
13
        vs.
                                                    13
                                                        2007, and the proceedings being taken down by
14 MYLAN LABORATORIES, INC.; MYLAN : No.: 98-3032G 14
                                                        Stenotype by JOMANNA DEROSA, and transcribed under
15 PHARMACEUTICALS INC.; NOVOPHARM : Judge:
                                                    15
                                                       her direction.
16 LTD., SCHEIN PHARMACEUTICAL, INC.; : William L.
                                                    16
17 TEVA PHARMACEUTICAL INDUSTRIES : Gary
                                                    17
18 LTD., TEVA PHARMACEUTICAL USA; :
                                                    18
19 and WATSON PHARMACEUTICALS, INC. :
                                                    19
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                                                    20
          Defendants.
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2 (Pages 2 to 5)

May 4, 2007

Page 76

New York, NY

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Page 74

A. The New York City Rand Institute was a 1 2 -- an extremely unsuccessful effort to a joint venture between the Rand Corporation and the City of New York to: 4

"Bring modern system science to problems of urban government."

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I worked largely in the areas of white collar productively, municipal labor relations, and spent a small amount of time on a health project advising an old charitable organization in New York about the organization and the future of the health services they provided.

13 At Columbia, I was a member of the faculty of the School of Public Health, the 14 15 faculty of the Department of Political Science 16 after a while, and had an appointment at a 17 research center, the Center For Community Health Systems, which did health services research on 19 urban health problems, and I taught and did

research and wrote on issues of health policy and 20 health care. 21

22 Q. In your positions with the Rand

Page 75

Institute and with Columbia University, did you 2 have any work involving reimbursement for prescription drugs? 3

A. Not that I'm aware of. I think there were a couple of articles or book reviews or things of that stuff in my early days at Columbia when I was still sort of looking for focus about the drug development process and about FDA regulation of -- of drugs and the drug development process, but not having to do with reimbursement, per se.

12 And as I began to focus more in 13 particular areas after a little while there, I 14 didn't do any work having to do with drugs or 15 drug pricing.

16 Q. Between 1979 and 1982, when you were Assistant Commissioner at the New Jersey State 17 18 Department of Health, did that position involve, 19 in any way, reimbursement for drugs?

20 A. No.

21 Q. From 1982 to 1983, while you were

assistant vice president at the Robert Wood 22

Johnson Foundation, did you have any exposure to 2 reimbursement for drugs?

3 A. No.

4 MS. BROOKER: Objection. Form. Sorry. 5 THE WITNESS: Sorry.

Q. Between 1983 and 1993, while you were 6 7 president of the United Hospital Fund, did that 8 have anything to do with reimbursement for 9 prescription drugs?

MS. BROOKER: Objection. Form.

A. That did not. Again, the New York AIDS Advisory Council was very much involved in issues of the pricing for AZT and some of the other first generation anti-retro virals.

15 Q. And -- and tell me what was the 16 involvement of the -- you said it was the 17 council?

18 A. The New York State AIDS Advisory 19 Council.

20 Q. The New York State AIDS Advisory Council. What was the involvement of the New 21

22 York State AIDS Advisory Council and issues of --

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Page 77

1 of drug reimbursement and pricing? 2

MS. BROOKER: Objection. Form.

A. Primarily to state objections to the level of the prices associated with the drugs, to encourage the FDA to expedite approval of competitor drugs to AZT, and to argue for discounts for the so-called ADAP program, which was a federally funded state-administered program

9 to help finance purchase of anti-HIV drugs for

10 non-Medicaid eligible patients.

11 Q. Now, at some point in 1993 you became 12 administrator of the Health Care Financing

13 Administration. Correct?

A. Yes, sir.

15 Q. Generally known by the acronym HCFA?

16 A. That's right.

17 Q. All caps, H-C-F-A.

18 When in 1993 did you become

19 administrator of HCFA?

A. I was sworn in in late May. I believe 20

21 the 22nd of it.

22 Q. And you held that position until 1997?

20 (Pages 74 to 77)

May 4, 2007

New York, NY

Page 78 Page 80 an issue of some significance. 1 A. That's correct. 2 Q. When in 1997 did you resign? 2 There are other issues of -- I think 3 A. My last day in that position was 3 that's -- there are -- there are certain issues 4 September 13th, 1997. 4 of -- having to do with legal matters that are 5 5 Q. Is there any activity, prior to May of assigned directly to the Inspector General, or in 1993, whether professional activity, employment, some cases -- and I don't know if this is by law 6 6 7 in which you had some involvement in or you 7 or regulation or just custom -- our reserve for 8 studied Medicare or Medicaid reimbursement for 8 the Department of Justice. 9 prescription drugs? 9 So, for example, when the agency is 10 MS. BROOKER: Objection. Form. 10 involved in civil litigation authority to enter A. Other than the issues with AIDS drugs into a settlement, it belongs with the Department 11 11 12 that I've just described, no. 12 of Justice. 13 Q. How did you come to be the 13 Again, I don't know whether that's 14 14 administrator for HCFA? statutory or regulatory. Things of that sort. 15 A. Well, I can't entirely answer that 15 Q. To whom did you report as administrator 16 question. I believe I was recommended to 16 of HCFA? Secretary Shalala by several mutual friends. And 17 A. Secretary Shalala. 18 I believe, for a variety of reasons, the White Q. I assume that some people reported to 18 you as well? 19 House in this case deferred to the Secretary for 19 20 a recommendation, although not on the final 20 A. Yes. decision. And then I went through a variety of Q. How many? 21 21 22 vetting processes. I came out the other end. 22 A. Well, the agency, in its entirety, Page 79 Page 81 1 Q. What were your job responsibilities as employed just over 4,000 people during my period administrator of HCFA? as administrator. The number of direct reports 2 3 A. Well, the major responsibilities are 3 was probably 10, plus or minus; 10 to 15, 4 administration of the Medicare and Medicaid 4 counting personal staff. 5 programs. Under the Social Security Act, almost 5 Q. Did you have, personally, much 6 all the administrative responsibilities are interaction with the regional offices for HCFA? 6 7 delegated to the Secretary. Almost all of those 7 A. I tried to, yes. -- for Titles 18 and 19, almost all of those are 8 Q. And how about state Medicaid agencies? redelegated to the administrator. 9 9 MS. BROOKER: Objection. Form. 10 10 A. We met quarterly with the Executive Q. What are not delegated? That was a Committee of the Association of State Medicaid 11 messy question. 11 12 What responsibilities for Medicare and 12 Directors. I tried to attend at least part of 13 Medicaid administration are not delegated by the 13 all those meetings. I also, for reasons ranging 14 Secretary to the administrator? 14 from pre-existing personal relationships to 15 A. Well, the --15 political sensitivities, had direct 16 16 MS. BROOKER: Objection. Form. communications from time to time with individual 17 A. -- the -- there is a -- a board of 17 state Medicaid directors. In most instances, I had very little 18 trustees for the hospital insurance supplementary 18 medical insurance trust funds, which are interaction with state Medicaid officials below 19 19 the director level. statutory. The HCFA administrator serves as 20 20 21 Secretary to both of those boards. Their only 21 Q. Would you have any interaction, while 22 actual authority is to issue reports, but that's 22 you were administrator of HCFA, with

21 (Pages 78 to 81)

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New York, NY

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Page 142

Q. And for a brand name drug, would you -- at the time, did you expect that there would be much variation between various purchasers based upon volume purchases of the brand name drug?

A. I believe we had a perception that the bigger the purchaser, the larger the discount they were likely to be able to achieve; that the very largest pharmacy chains, for instance, or hospital group purchasing operations, probably received the most favorable prices, but that that would be -- and that some small independent pharmacies might actually pay average wholesale price as described in the compendia; that there would be a range below that in which most of the prices would actually occur.

Q. Turning to generic drugs for a minute, what do you understand to be the differences between the market for brand name drugs and the market for generic drugs?

MS. BROOKER: Objection. Form.

- A. If we're going back to 1997 --
- Q. Correct.

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A. -- I think it's fair to say that I had really only a very limited understanding of the marketplace for generic drugs and an even more limited understanding of the difference between the market for generic drugs and for brand drugs.

And, again, my perception at the time was that that was likely more like a commodity market in which there was probably more purchasing power on the part of the large purchasers, but not the same ability to raise prices on the up-side to small purchasers that prevailed on the brand name side.

- Q. I'd like to focus you just for a minute, before we turn to a specific document, about a particular generic drug. I think you mentioned commodities. Are you familiar with sodium saline solution?
- 18 A. Yes.
- Q. It's a bag of salt water, essentially.
- 20 Correct?
- A. That's correct.
 - Q. Would you agree with me that you can't

get much more commoditized in a bag of salt water
in the drug market?

A. The only quibble I would provide to that question is I never really thought of it as classically being part of the pharmaceutical market. It was such a -- it was really a hospital supply kind of market. It was such a standard product that even though it was FDA regulated and -- and sterility issues were so

forth, it tended to be -- hospitals tend to stockit, for example, in sterile supplies, put it on

their cost report as part of sterile suppliesrather than through their pharmacies.

Q. But a home infusion provider reimbursed under Part B, for example, might be reimbursed for sodium saline solution.

Was that your understanding in '97? MS. BROOKER: Objection. Form.

A. Yes, but whether that was as a supply or a drug, I honestly couldn't tell you. I would have thought of it as a supply.

Q. Turning to the market of it, whether we

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call it a drug or -- or a supply, did you have an
 understanding, in 1997, of what the market would
 look like for a product such as sodium saline
 solution?
 MS. BROOKER: Objection. Form.

MS. BROOKER: Objection. Form. MR. BREEN: Objection. Form.

A. Yes, I did.

Q. And what was your understanding?

9 A. Well, I actually -- in the 1980s, I

10 believe, when I was first becoming involved in

11 some of these issues in health care economics was

12 the first development of hospital group

13 purchasing operations, and I recall -- and the

14 first widespread circulation of the -- of "Modern

15 Healthcare," the magazine, and I recall monthly

16 headlines in "Modern Healthcare" about group

17 purchasing operations being -- achieving

18 discounts of 98 and 99 percent in their purchase

19 of basic infusion products and sterile supplies.

So, my perception was that on the

supply market, which, again, I understood andstill would contend is actually a separate market

37 (Pages 142 to 145)

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New York, NY

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from the pharmaceutical market that list prices, 2 are essentially entirely meaningless and that only the weakest and smallest scale buyers pay 4 anything close to it.

Q. And so, as of 1993, for example, would you be surprised if a single bag of sodium saline solution sold to a provider who bought maybe five would pay \$10 per bag, and a large purchaser who bought a very large volume would pay less than a dollar?

MS. BROOKER: Objection. Form.

- 12 A. I would not have been surprised.
- 13 Q. Okay. So, to that extent that --
- 14 President Clinton referring to a 10-to-1 ratio is 15 something that would be consistent with your

16 understanding of that particular market.

17 Correct?

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MS. BROOKER: Objection. Form.

- Q. I'm sorry. You have to verbalize.
- 20 A. Again, I would have thought that market
- was a subset of the supplies market rather than 21 22

the drug market.

Page 147

- Q. That was my question. But you would have distinguished between the drug market, where
- 3 10-to-1 would not -- you would not expect to see. 4 Correct?
- 5 A. That's correct.
- 6 Q. And the supply market, where sodium
- saline solution would be found, where there could be a huge variation between a small purchaser
- 9 purchasing at list price and a very large
- 10 purchaser purchasing at 99 percent off of list

11 price?

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12 MS. BROOKER: Objection. Form.

- A. I would have made such a distinction. and I would not have been surprised to see those sorts of differentials of the supply market.
- Q. And in between the commodities supply 16 market of sodium saline and the patent-protected 17 18 market of a brand name drug, would you expect 19 generic drugs to be somewhere between those two 20 extremes?
- 21 MS. BROOKER: Objection. Form.
- 22 MR. BREEN: Objection. Form.

A. That would be a question I never

2 thought about before today. But today I would

- 3 say that we always made the distinction between -
- 4 - between drugs and -- and supplies. And, again,
- 5 I would fall back on the Medicare green eyeshade
- 6 distinction between what's sterile supplies and

7 what's pharmacy. 8

MR. COOK: Let's take a break.

9 THE VIDEOGRAPHER: The time is 11:28 10 a.m. We're going off the record, concluding Tape

- No. 2 in the deposition of Dr. Bruce Vladeck in 11
- the matter of In re Pharmaceutical Average 12
- Wholesale Price Litigation. 13

(Recess taken.)

THE VIDEOGRAPHER: The time is 11:46

16 a.m. We're going back on the record, starting

- 17 Tape No. 3 of the deposition of Dr. Bruce Vladeck
- in the matter of In re Pharmaceutical Average 18
- 19 Wholesale Price Litigation.
- 20 Q. Doctor, based upon what we were talking
- about just before the break, would it be fair to 21
- 22 say that while you were administrator of HCFA,

Page 149

- you did not understand published average
 - wholesale price to be the average of prices at
 - which wholesalers were selling their drugs to 3
 - 4 their customers?
 - 5 A. It would -- it would be fair to say
 - 6 that I did not believe it was, in fact, an
 - 7 empirical estimate, that rather it was a -- an
 - amount reported by the manufacturer to -- of the 8
 - compendium compilers or whatever, yes.
 - Q. And, again, akin to a sticker price?
 - 11 A. That's correct.
 - 12 Q. Where did you get that understanding?
 - 13 A. I believe that was probably what my

14 staff explained to me when I first encountered

- 15 the concept sometime after I took office. 16
- O. Do you recall anybody within HCFA who 17 was under the belief that average wholesale price 18 was an average of prices at which wholesalers

sold drugs to customers? 19

- 20 MS. BROOKER: Object to form. And I
- 21 would just instruct the witness, just, you know, 22 be mindful of not disclosing deliberations,

38 (Pages 146 to 149)

Vladeck, Ph.D., Bruce C. - Vol. II

June 21, 2007

New York, NY

	Paq	e	28	35
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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

-----X MDL NO. 1456

IN RE: PHARMACEUTICAL INDUSTRY : CIVIL ACTION:

AVERAGE WHOLESALE PRICE LITIGATION: 01-CV-12257-PBS

----X

THIS DOCUMENT RELATES TO: :

U.S. ex rel. Ven-A-Care of the : CIVIL ACTION:

Florida Keys, Inc. v. Abbott : 06-CV-11337-PBS

Laboratories, Inc. :

----X

IN THE CIRCUIT COURT OF

MONTGOMERY COUNTY, ALABAMA

----X

STATE OF ALABAMA, : CASE NO.

Plaintiff, : CV-05-219

v.

ABBOTT LABORATORIES, INC., : JUDGE

et al., : CHARLES PRICE

Defendants.

-----X

Henderson Legal Services 202-220-4158

Vladeck, Ph.D., Bruce C. - Vol. II New York, NY

June 21, 2007

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Page 286
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1 STATE OF WISCONSIN CIRCUIT COURT DANE COUNTY
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                                                         IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
   -----X
                                                                STATE OF MISSOURI
                                                       -----x
  STATE OF WISCONSIN,
                            : CASE NO.
                                                     3
4
       Plaintiff,
                 : 04-CV-1709
                                                        STATE OF MISSOURI, ex rel.,
5
                                                     5 JEREMIAH W. (JAY) NIXON,
  AMGEN INC., et al.,
6
                                                     6
                                                       Attorney General,
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      Defendants.
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                                                        MISSOURI DEPARTMENT OF SOCIAL
9
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                                                        SERVICES, DIVISION OF MEDICAL
                                                                                        : Case No.:
10
        IN THE COURT OF COMMON PLEAS
                                                    10 SERVICES,
                                                                             : 054-1216
         FIFTH JUDICIAL CIRCUIT
11
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                                                               Plaintiffs, : Division
   -----X
                                                    12
                                                                         : No. 31
   STATE OF SOUTH CAROLINA, and : STATE OF
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                                                             VS.
   HENRY D. McMASTER, in his official: SOUTH CAROLINA
14
                                                    14 DEY INC., DEY, L.P., MERCK KGaA, :
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   capacity as Attorney General for : COUNTY OF
                                                    15 EMD, INC., WARRICK
   the State of South Carolina, : RICHLAND
16
                                                    16 PHARMACEUTICALS CORPORATION,
17
       Plaintiff,
                                                    17 SCHERING-PLOUGH CORPORATION, and :
                  : CIVIL ACTION:
18
     v.
                                                    18 SCHERING CORPORATION,
19 MYLAN LABORATORIES, INC. : 07-CP-40-0283
                                                               Defendants.
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       Defendant.
                                                    20 ----x
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                                         Page 287
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     IN THE COURT OF THE SECOND JUDICIAL CIRCUIT
                                                     1
                                                                     New York, New York
2
        IN AND FOR LEON COUNTY, FLORIDA
                                                     2
                                                                     Thursday, June 21, 2007
  THE STATE OF FLORIDA
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4 ex rel.
                                                     4
                                                             CONTINUED Videotaped Deposition of
  -----X
                                                     5
                                                        BRUCE C. VLADECK, Ph.D., a witness herein, called
6 VEN-A-CARE OF THE FLORIDA
                                                        for examination by counsel for Abbott Laboratories
                                                     б
7 KEYS, INC., a Florida
                                                     7
                                                        in the above-entitled matter, pursuant to
  Corporation, by and through its :
                                                        Subpoena, the witness being duly sworn by JOMANNA
   principal officers and directors, :
                                                        DEROSA, a Notary Public in and for New York, taken
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   ZACHARY T. BENTLEY and
                                                    10
                                                        at the offices of Jones Day, 222 East 41st Street,
11 T. MARK JONES,
                                                    11 New York, New York, at 8:54 a.m. on Thursday, June
12
          Plaintiffs, :
                                                    12
                                                        21, 2007, and the proceedings being taken down by
13
                    : Civil Action
                                                    13
                                                        Stenotype by JOMANNA DEROSA, and transcribed under
        VS.
14 MYLAN LABORATORIES, INC.; MYLAN : No.: 98-3032G 14
                                                        her direction.
15 PHARMACEUTICALS INC.; NOVOPHARM : Judge:
                                                    15
16 LTD., SCHEIN PHARMACEUTICAL, INC.; : William L.
                                                    16
17 TEVA PHARMACEUTICAL INDUSTRIES : Gary
                                                    17
18 LTD., TEVA PHARMACEUTICAL USA; :
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19 and WATSON PHARMACEUTICALS, INC. :
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20
          Defendants.
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2 (Pages 286 to 289)

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Vladeck, Ph.D., Bruce C. - Vol. II New York, NY

June 21, 2007

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Page 462
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1 So, based on your understanding 2 when you were running HCFA, Dr. Vladeck, the state Medicaid people who were designing and 3 administering the reimbursement methodology of the 4 5 states would have, through HCFA, access to AMP, average manufacturer price, data. Right? 6 7

MS. BROOKER: Objection. Form. MR. BREEN: Objection. Form.

8 9 In the generic sense that the agencies -- the state agencies that administered 10 Medicaid would have access to it. Whether it was 11 12 the same people in those agencies who administered the rebate program and made policy about 13 14 reimbursement policy, I wouldn't know. 15 Okay. But in terms of -- let's --

let's talk in terms of agency, since people might change over time.

But the agencies that ran Medicaid in each of the states, which were the agencies responsible for implementing the reimbursement methodologies, those agencies would have access, through HCFA, to AMP data from the states.

Page 463

1 Right? 2

MS. BROOKER: Objection. Form.

3 A.

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So, for example, looking back at O. Exhibit Dey 022, the one-page sheet that we had that had all the reimbursement basis, the responsible directors of the Medicaid agencies of these -- of each of these states would be able to peruse AMP data and compare that to what they were 10 reimbursing on. Right?

MR. BREEN: Objection. Form. 11 MS. BROOKER: Objection. Form. 12 13

MR. BATES: Objection to form. When you talk about "perusing,"

14 15 again, I don't -- I don't know if they'd even be aware that their agencies had it. But if they 16 17 were, depending on how their agencies were 18 organized, they might very well be.

So, it was entirely -- it was 19 entirely possible for the heads of a state 20

21 Medicaid agency to look at the AMP data on AMP prices and at the same time look at data as to

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I don't know what you mean by "specified discounts," but it was my impression

18 for single-source drugs in the range of 15 to 20

19 20 generic drugs, as I've learned in the course of

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22 AWP, on average.

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1 what they were reimbursing for those drugs. That 2 was entirely possible. Right?

> MS. BROOKER: Objection. Form. MR. BREEN: Objection. Form.

It's -- I don't know any reason why

it wouldn't be possible. And within your agency, within

HCFA, certainly people within HCFA could sit down and compare the AMP data, for example, for Dey's Albuterol, and see what the AMP was and compare what the AWP was. Right?

That was -- that was information that they had in the agency?

MS. BROOKER: Objection. Form.

I believe the -- the way we A. interpreted the confidentiality provisions of the statute was that the people directly involved in the administration of the Medicaid drug rebate program could have chosen to do so, yes.

Right. So, somebody in -- in HCFA that was involved with the rebate program could one day look at the AMP for Dey's Albuterol and

1 compare it to an AWP for Dey's Albuterol? 2 MS. BROOKER: Objection. Form.

> Presumably, yes. A.

And based on your understanding of AWP and AMP, as you've indicated in the course of this deposition and your prior session, you would expect that the AWP -- there was a spread between the AMP and the AWP. Right?

MS. BROOKER: Objection. Form.

Yes.

O. And that would be because the AMP reported to HCFA would include a number of specified discounts. Isn't that right?

MS. BROOKER: Objection. Form.

that, again, on average, the AMPs would have been

percent below the AWP, on average, and, for

this proceeding, as much as 25 to 40 percent below

46 (Pages 462 to 465)

Vladeck, Ph.D., Bruce C. - Vol. II

June 21, 2007

New York, NY

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1	Q. Well, whatever the spread was, the	1	A. That's my understanding, yes.
2	information was available to people within HCFA to		Q. Now, was there any provision that
3	calculate it precisely. Isn't that right?	3	you're aware of in any statute or law or anything
4	MS. BROOKER: Objection. Form.	4	that told manufacturers that they had to report
5	A. If they had any reason to calculate	5	average wholesale price in a particular way,
6	it precisely.	6	similar to the way AMP is described?
7	Q. The information was all at HCFA to	7	MS. CONNOLLY: Objection to form.
8	do that. Right?	8	A. No. I'm not familiar of specific
9	MR. BREEN: Objection. Form.	9	instructions about reporting AWP.
10	MS. BROOKER: Objection. Form.	10	Q. And as far as you know no such
11	A. I guess it was, to the extent it	11	instructions existed.
12	was accurate.	12	A. I don't know of any, no.
13	MR. ESCOBAR: Thank you. We'll	13	Q. Now, if you turn to Page 7 of the -
14	take a break.	14	- of the agreement itself in Exhibit Dey 023,
15	THE VIDEOGRAPHER: The time is	15	there's a Section 3 there entitled "Secretary's
16	12:32 p.m. We're going off the record, concluding	16	Responsibilities"?
17	Tape No. 8 in the deposition of Dr. Bruce Vladeck	17	Do you see that?
18	in the matter of In re Pharmaceutical Industry	18	A. Yes.
19	Average Wholesale Price Litigation.	19	Q. And that section indicates the
20	(Luncheon recess: 12:32 p.m.)	20	responsibilities that the Secretary of Health and
21	THE VIDEOGRAPHER: The time is 1:38		Human Services has under the agreement?
22	p.m. We're going back on the record, starting	22	A. Yes.
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1	with Tape No. 9.	1	Q. And those responsibilities
2	Q. Dr. Vladeck, we're back on the	2	strike that.
3	record.	3	One of the things that the
4	Did you discuss your testimony with	4	Secretary had and the manufacturer agreed to were
5	anyone?	5	that HHS could survey manufacturers to verify
_	A. No.	_	that THIS could survey manufacturers to verify
6	71. 110.	6	manufacturer prices. Right?
6 7	Q. If you go back to Exhibit Dey 023,	7	manufacturer prices. Right? MS. BROOKER: Objection. Form.
		7 8	manufacturer prices. Right? MS. BROOKER: Objection. Form. A. That's what it says, yes.
7 8 9	Q. If you go back to Exhibit Dey 023, which is a copy of the rebate agreement? Other than the rebate agreement,	7	manufacturer prices. Right? MS. BROOKER: Objection. Form. A. That's what it says, yes. Q. During your tenure as the head of
7 8	Q. If you go back to Exhibit Dey 023, which is a copy of the rebate agreement? Other than the rebate agreement, are you aware of any other contract or agreement	7 8	manufacturer prices. Right? MS. BROOKER: Objection. Form. A. That's what it says, yes. Q. During your tenure as the head of HCFA, do you know whether the department went out
7 8 9 10 11	Q. If you go back to Exhibit Dey 023, which is a copy of the rebate agreement? Other than the rebate agreement, are you aware of any other contract or agreement that manufacturers had to enter into in connection	7 8 9 10 11	manufacturer prices. Right? MS. BROOKER: Objection. Form. A. That's what it says, yes. Q. During your tenure as the head of HCFA, do you know whether the department went out and did anything to verify the manufacturer prices
7 8 9 10 11 12	Q. If you go back to Exhibit Dey 023, which is a copy of the rebate agreement? Other than the rebate agreement, are you aware of any other contract or agreement that manufacturers had to enter into in connection with having drugs reimbursed by Medicaid?	7 8 9 10 11 12	manufacturer prices. Right? MS. BROOKER: Objection. Form. A. That's what it says, yes. Q. During your tenure as the head of HCFA, do you know whether the department went out and did anything to verify the manufacturer prices of any manufacturer?
7 8 9 10 11 12 13	Q. If you go back to Exhibit Dey 023, which is a copy of the rebate agreement? Other than the rebate agreement, are you aware of any other contract or agreement that manufacturers had to enter into in connection with having drugs reimbursed by Medicaid? A. No.	7 8 9 10 11 12 13	manufacturer prices. Right? MS. BROOKER: Objection. Form. A. That's what it says, yes. Q. During your tenure as the head of HCFA, do you know whether the department went out and did anything to verify the manufacturer prices of any manufacturer? A. I'm not aware of any surveys, no.
7 8 9 10 11 12 13 14	Q. If you go back to Exhibit Dey 023, which is a copy of the rebate agreement? Other than the rebate agreement, are you aware of any other contract or agreement that manufacturers had to enter into in connection with having drugs reimbursed by Medicaid? A. No. Q. And the rebate agreement, is it	7 8 9 10 11 12 13 14	manufacturer prices. Right? MS. BROOKER: Objection. Form. A. That's what it says, yes. Q. During your tenure as the head of HCFA, do you know whether the department went out and did anything to verify the manufacturer prices of any manufacturer? A. I'm not aware of any surveys, no. Q. As far as you know, your agency,
7 8 9 10 11 12 13 14 15	Q. If you go back to Exhibit Dey 023, which is a copy of the rebate agreement? Other than the rebate agreement, are you aware of any other contract or agreement that manufacturers had to enter into in connection with having drugs reimbursed by Medicaid? A. No. Q. And the rebate agreement, is it your understanding that the rebate agreement is	7 8 9 10 11 12 13 14 15	manufacturer prices. Right? MS. BROOKER: Objection. Form. A. That's what it says, yes. Q. During your tenure as the head of HCFA, do you know whether the department went out and did anything to verify the manufacturer prices of any manufacturer? A. I'm not aware of any surveys, no. Q. As far as you know, your agency, HCFA, could have called manufacturers to ask them
7 8 9 10 11 12 13 14 15 16	Q. If you go back to Exhibit Dey 023, which is a copy of the rebate agreement? Other than the rebate agreement, are you aware of any other contract or agreement that manufacturers had to enter into in connection with having drugs reimbursed by Medicaid? A. No. Q. And the rebate agreement, is it your understanding that the rebate agreement is entered into by the manufacturer on one side and	7 8 9 10 11 12 13 14 15 16	manufacturer prices. Right? MS. BROOKER: Objection. Form. A. That's what it says, yes. Q. During your tenure as the head of HCFA, do you know whether the department went out and did anything to verify the manufacturer prices of any manufacturer? A. I'm not aware of any surveys, no. Q. As far as you know, your agency, HCFA, could have called manufacturers to ask them to tell HCFA exactly how they calculated average
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7 8 9 10 11 12 13 14 15 16 17	Q. If you go back to Exhibit Dey 023, which is a copy of the rebate agreement? Other than the rebate agreement, are you aware of any other contract or agreement that manufacturers had to enter into in connection with having drugs reimbursed by Medicaid? A. No. Q. And the rebate agreement, is it your understanding that the rebate agreement is entered into by the manufacturer on one side and by the Secretary on behalf of HHS and all the states?	7 8 9 10 11 12 13 14 15 16 17	manufacturer prices. Right? MS. BROOKER: Objection. Form. A. That's what it says, yes. Q. During your tenure as the head of HCFA, do you know whether the department went out and did anything to verify the manufacturer prices of any manufacturer? A. I'm not aware of any surveys, no. Q. As far as you know, your agency, HCFA, could have called manufacturers to ask them to tell HCFA exactly how they calculated average wholesale price. You could have done that, right? MS. LIANG: Objection.
7 8 9 10 11 12 13 14 15 16 17 18	Q. If you go back to Exhibit Dey 023, which is a copy of the rebate agreement? Other than the rebate agreement, are you aware of any other contract or agreement that manufacturers had to enter into in connection with having drugs reimbursed by Medicaid? A. No. Q. And the rebate agreement, is it your understanding that the rebate agreement is entered into by the manufacturer on one side and by the Secretary on behalf of HHS and all the states? A. That's my understanding.	7 8 9 10 11 12 13 14 15 16 17 18	manufacturer prices. Right? MS. BROOKER: Objection. Form. A. That's what it says, yes. Q. During your tenure as the head of HCFA, do you know whether the department went out and did anything to verify the manufacturer prices of any manufacturer? A. I'm not aware of any surveys, no. Q. As far as you know, your agency, HCFA, could have called manufacturers to ask them to tell HCFA exactly how they calculated average wholesale price. You could have done that, right? MS. LIANG: Objection. MS. BROOKER: Objection. Form.
7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. If you go back to Exhibit Dey 023, which is a copy of the rebate agreement? Other than the rebate agreement, are you aware of any other contract or agreement that manufacturers had to enter into in connection with having drugs reimbursed by Medicaid? A. No. Q. And the rebate agreement, is it your understanding that the rebate agreement is entered into by the manufacturer on one side and by the Secretary on behalf of HHS and all the states? A. That's my understanding. Q. So then as far as you understood	7 8 9 10 11 12 13 14 15 16 17 18 19 20	manufacturer prices. Right? MS. BROOKER: Objection. Form. A. That's what it says, yes. Q. During your tenure as the head of HCFA, do you know whether the department went out and did anything to verify the manufacturer prices of any manufacturer? A. I'm not aware of any surveys, no. Q. As far as you know, your agency, HCFA, could have called manufacturers to ask them to tell HCFA exactly how they calculated average wholesale price. You could have done that, right? MS. LIANG: Objection. MS. BROOKER: Objection. Form. A. We certainly could have, yes.
7 8 9 10 11 12 13 14 15 16 17 18	Q. If you go back to Exhibit Dey 023, which is a copy of the rebate agreement? Other than the rebate agreement, are you aware of any other contract or agreement that manufacturers had to enter into in connection with having drugs reimbursed by Medicaid? A. No. Q. And the rebate agreement, is it your understanding that the rebate agreement is entered into by the manufacturer on one side and by the Secretary on behalf of HHS and all the states? A. That's my understanding.	7 8 9 10 11 12 13 14 15 16 17 18	manufacturer prices. Right? MS. BROOKER: Objection. Form. A. That's what it says, yes. Q. During your tenure as the head of HCFA, do you know whether the department went out and did anything to verify the manufacturer prices of any manufacturer? A. I'm not aware of any surveys, no. Q. As far as you know, your agency, HCFA, could have called manufacturers to ask them to tell HCFA exactly how they calculated average wholesale price. You could have done that, right? MS. LIANG: Objection. MS. BROOKER: Objection. Form.

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